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the FEDERAL REGISTER. EPA will use the same criteria and procedures for modification as for establishing tolerances under this part.

§ 176.15 Effect of a tolerance.

The establishment of a tolerance under this part does not alter the requirement that any applicant comply with procedures established in part 166 of this chapter for emergency exemptions of FIFRA.

PART 177—ISSUANCE OF FOOD ADDITIVE REGULATIONS

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AUTHORITY: 21 U.S.C. 348, 371(a) 331(j); Reorg. Plan No. 3 of 1970.

SOURCE: 55 FR 50288, Dec. 5, 1990, unless otherwise noted.

Subpart A—General Provisions

§ 177.1 Scope and applicability.

(a) This part establishes procedures for the establishment, modification, or revocation by the Administrator of food additive regulations under section 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 348, for food additives which may result in pesticide residues in or on processed food or otherwise affect the characteristics of such food.

(b) Part 178 of this chapter contains procedures for filing objections and requests for hearings under FFDCA section 409(f) on food additive regulations or petition denials issued under this part. Part 179 of this chapter contains rules governing formal evidentiary hearings under FFDCA section 409(f).

(c) Part 180 of this chapter contains regulations establishing tolerances, or exemptions from the necessity for a tolerance, for pesticide residues on raw agricultural commodities under FFDCA section 408. If the use of a pesticide chemical in the production, storage, or transportation of a raw agricultural commodity (RAC) in conformity with such a tolerance or exemption results in the presence of a pesticide residue in or on processed food made from the RAC, FFDCA section 402(a)(2)(C) provides that such pesticide residue shall not be deemed unsafe for the purposes of FFDCA section 409 (despite the absence of a food additive regulation regarding such residue on the processed food) if the residue in or on the RAC has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the RAC. However, a food additive regulation would be required if the level of the pesticide residue in the processed food when ready to eat exceeded the level permitted in the “parent” RAC by the tolerance established under FFDCA section 408. In addition, if a pesticide residue in or on a processed food results from the application of a pesticide during or after processing, the food would be unsafe

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within the meaning of FFDCA section 409 unless a food additive regulation permitted that residue in or on the processed food.

§ 177.3 Definitions.

For the purposes of this part:

Administrator means the Administrator of the Agency, or an officer or employee of the Agency to whom the Administrator has delegated the authority to perform functions under this part.

Agency means the United States Environmental Protection Agency.

FFDCA means the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. 301–392.

FIFRA means the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136–136y.

Food additive means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component of or otherwise affecting the characteristics of any food (including any such substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food), except that such term does not include:

(1) A pesticide chemical in or on a raw agricultural commodity.

(2) A pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity.

(3) A color additive.

(4) Any substance used in accordance with a sanction or approval granted prior to September 6, 1958, pursuant to the FFDCA, the Poultry Products Inspection Act, or the Federal Meat Inspection Act.

(5) A new animal drug.

(6) A substance that is generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use.

Food additive regulation means a regulation issued pursuant to FFDCA section 409 that states the conditions under which a food additive may be safely used. A food additive regulation under this part ordinarily establishes a tolerance for pesticide residues in or on a particular processed food or a group of such foods. It may also specify:

(1) The particular food or classes of food in or on which a food additive may be used.

(2) The maximum quantity of the food additive which may be used in or on such food.

(3) The manner in which the food additive may be added to or used in or on such food.

(4) Directions or other labeling or packaging requirements for the food additive.

Pesticide chemical means any substance which alone, or in chemical combination with or in formulation with one or more other substances, is a “pesticide” within the meaning of FIFRA and which is used in the production, storage, or transportation of any raw agricultural commodity or processed food. The term includes any substance that is an active ingredient, intentionally-added inert ingredient, or impurity of such a “pesticide.”

Pesticide residue means a residue of a pesticide chemical or of any metabolite or degradation product of a pesticide chemical.

Tolerance means:

(1) The amount of a pesticide residue that legally may be present in or on a raw agricultural commodity under the terms of a tolerance under FFDCA section 408 or a processed food under the terms of a food additive regulation under FFDCA section 409. Tolerances are usually expressed in terms of parts of the pesticide residue per million parts of the food (ppm), by weight.

(2) [Reserved]

Subparts B–D [Reserved]

Subpart E—Procedures for Filing Petitions**§ 177.81 Petition for establishment, modification, or revocation of a food additive regulation.**

(a) *Who may submit a petition.* Any person may submit a petition requesting the Agency to issue a regulation to establish, modify, or revoke a food additive regulation.

(b) *Where to submit petition.* A petition shall be submitted to: Office of Pesticide Programs (H7504C), Document Processing Desk - PETN, U. S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

(c) *Identification of petitioner.* A petition must be signed by the petitioner or the petitioner's authorized representative, and must state the petitioner's mailing address and telephone number.

(d) *Material to be in English language.* The petition shall be written in the English language. If any part of the accompanying material is written in a language other than English, it shall be accompanied by an accurate and complete English translation.

(e) *Format for data submission.* Data and information submitted in support of a petition shall be on separate sheets or sets of sheets of paper, suitably identified. If an item of data has already been submitted to the Agency, the petitioner may cite it rather than resubmitting it. The data shall be submitted in the manner specified by § 158.32 of this chapter.

(f) *Confidentiality of data and information in petition, amendment, or supplement—(1) Asserting confidentiality claims.* A petitioner may assert a claim that data and information in a petition, or any amendment or supplement to a petition, other than the summary described in § 177.102(j), are entitled to confidential treatment under part 2 of this chapter. To assert such a claim, the petitioner must mark those portions of the petition, amendment, or supplement, and those portions of any data and information submitted in support of the petition, amendment, or supplement, with the words “trade secret,” “proprietary,” or other words that indicate the data or information

are claimed to be confidential business information. If the data and information have also been submitted to EPA under FIFRA, the person shall assert the confidentiality claim in accordance with § 158.33 of this chapter.

(2) *Effect of asserting confidentiality claim.* If a petitioner asserts a confidentiality claim in accordance with this paragraph for any data or information in a petition, amendment, or supplement, the Agency will disclose that data or information only in accordance with parts 2, 158, 178, and 179, of this chapter, and FIFRA and FFDCA, as applicable.

(3) *Failure to assert confidentiality claim.* If a petitioner does not assert a claim that specific data and information in a petition, or any amendment or supplement to a petition, are entitled to confidential treatment under part 2 of this chapter in accordance with paragraph (e)(1) of this section at the time of submission of the petition, amendment, or supplement, the Agency will treat that data and information as available for disclosure to the public without further notice to the petitioner.

§ 177.84 Deficient or incomplete petitions.

(a) After a preliminary review of the petition, the Administrator may notify the petitioner that the Agency has found the petition to be incomplete or deficient, i.e., that it does not comply with the requirements of § 177.102 or § 177.105, and that it will not be accepted for detailed review.

(b) A petitioner who receives a notice under paragraph (a) of this section may supplement the petition, in which case the Agency shall conduct a further preliminary review of the petition as supplemented and take action under paragraph (a) of this section or under § 177.86.

§ 177.86 Acceptance for review.

Unless the Administrator notifies the petitioner under § 177.84 that the petition is incomplete or deficient, the Administrator shall accept the petition for detailed review.

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§ 177.88 Publication of notice.

Within 30 days of acceptance of a petition for detailed review, the Administrator shall publish in the FEDERAL REGISTER a notice which includes the name of the petitioner and the summary submitted in accordance with § 177.102(j).

§ 177.92 Amendments or supplements to petitions.

After a notice of a petition has been published, the petitioner may submit additional information or data in support of the petition, or may amend the petition. Any such submission or amendment shall be accompanied by an informative summary of its contents that may be published in the FEDERAL REGISTER. The Administrator shall publish a notice in the FEDERAL REGISTER to supplement the notice published under § 177.88 if:

(a) The petitioner seeks to amend the petition by:

(1) Increasing a requested tolerance, by identifying any additional food additive or additional pesticide residues to which the requested food additive regulation would apply.

(2) Identifying any additional processed food to which the requested food additive regulation would apply.

(3) Changing the method for detecting or measuring pesticide residues to be used for enforcement purposes.

(b) The Administrator finds that publication of such a notice otherwise would be in the public interest.

§ 177.98 Withdrawal of petitions.

A petitioner may withdraw a petition. The Agency may retain a copy of a withdrawn petition and any supporting data and information.

§ 177.99 Demand for action.

A petitioner may demand action on a petition if the Administrator has not acted on the petition within the timeframes in FFDCA section 409(c)(2). Upon receipt of such a demand, the Administrator shall take appropriate action under FFDCA section 409(c)(1).

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Subpart F—Submission of Scientific and Technical Information

§ 177.102 Data and information required to support petition to establish a food additive regulation, to increase a tolerance, or to remove a condition on use.

A petition to establish a food additive regulation, or to modify a food additive regulation by increasing a tolerance for a pesticide residue in or on a processed food or by removing any other condition of use of a food additive, shall include the following data and information:

(a)(1) The name and composition of the food additive that is a subject of the petition, and the chemical composition of each component of the food additive.

(2) The name, chemical identity, and composition of each pesticide residue that is a subject of the petition.

(3) The identity of the processed food(s) in question.

(b) A statement of any conditions of use proposed for the food additive, including all directions, recommendations, and suggestions proposed regarding the use of the food additive, i.e., the amount, frequency, method, and time of application or other use, and a copy of its proposed labeling.

(c) Full reports of investigations made with respect to the toxicity of the food additive and of its safety for the proposed use, including full information as to the methods and controls used in conducting such investigations.

(d) The results of tests to determine the identity and amount of pesticide residues in or on the processed food resulting from the proposed use of the food additive, including a description of the analytical methods used, and a description of practicable methods for measuring such pesticide residues.

(e) Full reports of investigations made with respect to the toxicity of such pesticide residues, including full information as to the methods and controls used in conducting such investigations.

(f) All relevant data bearing on the physical or other technical effects such food additive is intended to produce, and the quantity of such food additive required to produce such effect.

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(g) The terms of each food additive regulation proposed.

(h) Any other information relevant to the approval of the petition known to the petitioner that is unfavorable to the petition.

(i) A statement of why, in the petitioner's opinion, it would be reasonable for the Administrator to approve the petition, taking into account the terms of the FFDCA and FIFRA, this part, the petition, the data and information submitted or cited in support of the petition, and other information available to the Agency.

(j) An informative summary of the petition and of the data, information, and arguments submitted or cited in support of the petition, and a statement that the petitioner agrees that such summary or any information it contains may be published as a part of the notice to be furnished to the public under § 177.88 or as part of a proposal under § 177.130. The summary need not refer to any method or process that is entitled to protection as a trade secret under FFDCA section 301(j).

[55 FR 50288, Dec. 5, 1990, as amended at 58 FR 34203, June 23, 1993]

§ 177.105 Data and information required to support petition to revoke a food additive regulation, to decrease a tolerance, or to add a condition on use.

A petition to revoke a food additive regulation, or to modify such a regulation by decreasing a tolerance for a pesticide residue in or on a processed food or by adding a condition on the use of a food additive, shall include:

(a) The data and information required by § 177.102(a), (b), (g), (h), and (i).

(b) Such data and information of the types described in § 177.102(c), (d), (e), and (f) as the petitioner chooses to submit.

(c) Information showing what changes, if any, petitioner believes would have to be made in associated registrations of pesticides under FIFRA or in associated tolerance regulations issued under FFDCA section 408 if the petition were granted.

[55 FR 50288, Dec. 5, 1990, as amended at 58 FR 34203, June 23, 1993]

§ 177.110 Additional data requirements; waiver of requirements.

(a) The Administrator may require or occasion a petitioner to submit data or information other than that described by this part only if the Administrator finds such data or information to be necessary for the evaluation of the petition.

(b) The Administrator may waive a requirement imposed by this part for the submission of data or information if the Administrator finds such data or information to be unnecessary for the evaluation of the petition.

[55 FR 50288, Dec. 5, 1990, as amended at 58 FR 34203, June 23, 1993]

§ 177.116 Sample of food additive.

The Agency may require the petitioner to submit a sample of the food additive or pesticide residue that is a subject of the petition. The Agency shall specify in such request the quantity which it requires.

[55 FR 50288, Dec. 5, 1990, as amended at 58 FR 34203, June 23, 1993]

Subpart G—Administrative Actions

§ 177.125 Action after review.

(a) After a petition has been accepted for detailed review, the Administrator shall review the petition, the accompanying data and information, and other pertinent data or information available to the Administrator.

(b) Upon completion of such review, the Administrator shall determine, in accordance with the Act, whether to issue an order that establishes, modifies, or revokes a food additive regulation (whether or not in accord with the action proposed by the petitioner), whether to issue an order denying the petition, or whether to publish a proposed food additive regulation and request public comment thereon under § 177.130.

(c) The Administrator shall publish in the FEDERAL REGISTER such order or proposed regulation. An order published under this section shall describe briefly how to submit objections and requests for a hearing under part 178 of this chapter.

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§ 177.130 Issuance of proposed rule on Administrator's initiative or in response to petition, and final action on proposal.

(a) The Administrator may publish in the FEDERAL REGISTER a proposal to establish a food additive regulation or to modify or revoke an existing food additive regulation, on his or her own initiative or in response to a petition.

(b) The Administrator shall provide a period of not less than 30 days for persons to comment on the proposed regulation.

(c) After reviewing any timely comments made, the Administrator may by order establish, modify, or revoke a food additive regulation, or may by order decide that no final action on the proposal is warranted. Each such order and each such regulation shall be published in the FEDERAL REGISTER. An order published under this section shall state that objections and requests for a hearing may be filed as prescribed by part 178 of this chapter.

§ 177.135 Effective date of regulation.

Any final regulation issued under § 177.125 or § 177.130 shall be effective on the date of publication in the FEDERAL REGISTER unless otherwise provided in the regulation. The Administrator, in his or her sole discretion, may stay the effective date of the regulation if an adversely affected person files an objection under part 178 of this chapter.

Subpart H—Judicial Review

§ 177.140 Judicial review.

The FFDCA does not provide for judicial review of an order or regulation issued under this part or of a denial of a petition under this part. However, if an objection to such action is submitted to the Administrator in the manner prescribed by part 178 of this chapter, judicial review may be obtained of the Administrator's action on the objection. (See FFDCA sections 409(f) and (g).)

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PART 178—OBJECTIONS AND REQUESTS FOR HEARINGS

Subpart A—General Provisions

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178.3 Definitions.

Subpart B—Procedures for Filing Objections and Requests for Hearing

178.20 Right to submit objections and requests for a hearing.

178.25 Form and manner of submission of objections.

178.27 Form and manner of submission of request for evidentiary hearing.

178.30 Response by Administrator to objections and to requests for hearing.

178.32 Rulings on requests for hearing.

178.35 Modification or revocation of regulation.

178.37 Order responding to objections on which a hearing was not requested or was denied.

Subpart C [Reserved]

Subpart D—Judicial Review

178.65 Judicial review.

178.70 Administrative record.

AUTHORITY: 21 U.S.C. 346a, 348, 371(a); Reorg. Plan No. 3 of 1970.

SOURCE: 55 FR 50291, Dec. 5, 1990, unless otherwise noted.

Subpart A—General Provisions

§ 178.3 Definitions.

For the purposes of this part:

Administrator means the Administrator of the Agency, or any officer or employee of the Agency to whom the Administrator delegates the authority to perform functions under this part.

Agency means the United States Environmental Protection Agency.

Assistant Administrator means the Agency's Assistant Administrator for Prevention, Pesticides and Toxic Substances, or any officer or employee of the Agency's Office of Prevention, Pesticides and Toxic Substances to whom the Assistant Administrator delegates the authority to perform functions under this part.

FFDCA means the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. 301–392.

[55 FR 50291, Dec. 5, 1990, as amended at 57 FR 28087, June 24, 1992]